

§ 640.120

times the antibody level of the Reference Immune Serum Globulin.

(c) *Reference materials.* The following reference materials shall be obtained from the Center for Biologics Evaluation and Research:

(1) Reference Immune Serum Globulin for correlation of measles antibody titers.

(2) Reference Immune Serum Globulin for correlation of poliomyelitis antibody titers, Types 1, 2, and 3.

[38 FR 32089, Nov. 20, 1973, as amended at 39 FR 9661, Mar. 13, 1974; 49 FR 23834, June 8, 1984; 50 FR 4140, Jan. 29, 1985; 55 FR 11013, Mar. 26, 1990]

Subpart K [Reserved]

Subpart L—Alternative Procedures

§ 640.120 Alternative procedures.

(a) The Director, Center for Biologics Evaluation and Research, may approve an exception or alternative to any requirement in subchapter F of chapter I of title 21 of the Code of Federal Regulations regarding blood, blood components, or blood products. Requests for such exceptions or alternatives shall ordinarily be in writing. Licensed establishments shall submit such requests in accordance with § 601.12 of this chapter. However, in limited circumstances, such requests may be made orally and permission may be given orally by the Director. Oral requests and approvals must be promptly followed by written requests and written approvals.

(b) FDA will publish a list of approved alternative procedures and exceptions periodically in the FEDERAL REGISTER.

[55 FR 10423, Mar. 21, 1990, as amended at 62 FR 39903, July 24, 1997]

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

Subpart A—Antibody to Hepatitis B Surface Antigen

Sec.

660.1 Antibody to Hepatitis B Surface Antigen.

660.2 General requirements.

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660.3 Reference panel.

660.4 Potency test.

660.5 Specificity.

660.6 Samples; protocols; official release.

Subpart B [Reserved]

Subpart C—Blood Grouping Reagent

660.20 Blood Grouping Reagent.

660.21 Processing.

660.22 Potency requirements with reference preparations.

660.25 Potency tests without reference preparations.

660.26 Specificity tests and avidity tests.

660.28 Labeling.

Subpart D—Reagent Red Blood Cells

660.30 Reagent Red Blood Cells.

660.31 Suitability of the donor.

660.32 Collection of source material.

660.33 Testing of source material.

660.34 Processing.

660.35 Labeling.

660.36 Samples and protocols.

Subpart E—Hepatitis B Surface Antigen

660.40 Hepatitis B Surface Antigen.

660.41 Processing.

660.42 Reference panel.

660.43 Potency test.

660.44 Specificity.

660.45 Labeling.

660.46 Samples; protocols; official release.

Subpart F—Anti-Human Globulin

660.50 Anti-Human Globulin.

660.51 Processing.

660.52 Reference preparations.

660.53 Controls for serological procedures.

660.54 Potency tests, specificity tests, tests for heterospecific antibodies, and additional tests for nonspecific properties.

660.55 Labeling.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—Antibody to Hepatitis B Surface Antigen

§ 660.1 Antibody to Hepatitis B Surface Antigen.

(a) *Proper name and definition.* The proper name of this product shall be